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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/648,985   | 08/27/2003  | Gary Searle          | 03-042-GS           | 4357             |
| 32118  | 7590        | 11/12/2004           | EXAMINER            |                  |
| LAMBERT & ASSOCIATES, P.L.L.C.<br>92 STATE STREET<br>BOSTON, MA 02109-2004 |             |                      | WEBB, SARAH K       |                  |
|  |             |                      | ART UNIT            | PAPER NUMBER     |
|  |             |                      | 3731                |                  |
| DATE MAILED: 11/12/2004  |             |                      |                     |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/648,985

Applicant(s)

SEARLE, GARY

Examiner

Sarah K Webb

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2004.
- 2a) ☐ This action is **FINAL**.      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-75 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-75 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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**DETAILED ACTION**

***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-23, drawn to a stent, classified in class 623, subclass 1.15.
  - II. Claim 24, drawn to a method of bonding, classified in class 623, subclass 901.
  - III. Claim 25, drawn to a method of rolling material, classified in class 623, subclass 901.
  - IV. Claim 26, drawn to a method of heat sealing, classified in class 623, subclass 901.
  - V. Claims 27-52, drawn to a balloon, classified in class 606, subclass 194.
  - VI. Claims 53-70, drawn to an internal ligation device, classified in class 606, subclass 228.
  - VII. Claims 71-75, drawn to a method of ligating, classified in class 606, subclass 222.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions II, III, IV and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the stent could be made by different processes.

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3. Inventions I and V are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention V has separate utility such as dilating a vessel alone without a stent. The stent could be deployed by other means than the balloon, such as a retracting sheath, as well known in the art. See MPEP § 806.05(d).

4. Inventions I and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions.

5. Inventions VI and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the device could be operated using different steps.

6. This application contains claims directed to the following patentably distinct species of the claimed invention.

**Group I** contains many species, so if applicant elects Group I, applicant must further elect a subspecies from each of the following lists:

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**STRUCTURE**

- a. Figures 1a-d
- b. Figures 8a-e
- c. Figures 9a-c
- d. Figures 10a-e
- e. Figures 11a-c
- f. Figures 12a-c

**MATERIAL OF STENT**

- g. Stainless steel
- h. Elgiloy

**BARRIER FILM MATERIAL**

- i. PP
- j. PTFE

**FILLER MATERIAL**

- k. Casein
- l. Superabsorbent polymer
- m. Hygroscopic polymer

**Group V** contains many species, so if applicant elects Group V, applicant must further

elect a subspecies from each of the following lists:

**FILLER MATERIAL**

- a. Claim 33
- b. Claim 34
- c. Claim 35
- d. Claim 36
- e. Claim 37

**BALLOON MATERIAL**

- f. Latex
- g. Silicon
- h. PP
- i. PTFE

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**RIGID BAND**

- j. Stainless steel
- k. Elgiloy

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a **listing of all claims readable thereon**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarah K Webb whose

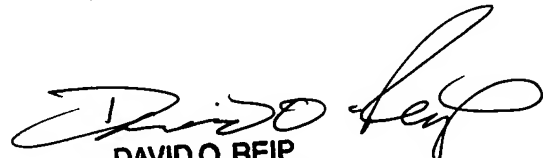
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telephone number is (571) 272-4706. The examiner can normally be reached on Mon-Fri 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SKW  
11/09/04



DAVID O. REIP  
PRIMARY EXAMINER